

Service Manual

KC 1 
Amelung

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2. Appliance properties and technical data

2.1 Appliance description

The Amelung KC1Δ is a semi-automatic mechanical clot recognition system that is used to determine prothrombin times (PT), activated partial thromboplastic times (APTT) and fibrinogen concentrations, as well as other clotting tests. The KC1Δ can be used for all clotting time tests which end in the formation of fibrin. Both plasma and full blood can be used as samples in conjunction with appropriate reagents. Both the sample and the reagents are added by hand. The time to clotting is measured automatically. If the parameters are specified correctly, ratio and INR are calculated automatically using the prothrombin times.

2.2 Technical data

Type:

Semi-automatic clot analysis machine; table-top

Control:

with P2864 thermal printer (optional)

Operating principle:

Ball method

Measuring channels:

1 (mechanical)

Display:

Liquid crystal display (LCD)

Incubation stations:

4

Reagent stations:

1

Dimensions:

Height: 80 mm

Width: 140 mm

Depth: 210 mm [270 mm]

Weight:

1.2 kg

Electrical specifications:

Primary voltage: 100–240 V / 50–60 Hz

Secondary voltage: 12 V

Power consumption: 40 VA (maximum)

Temperature control:

Measuring module: 37.3. °C ±0.5. °C

Measuring time:

minimum: 4.6 seconds

maximum: 999.9 seconds

2.3 Legend

see also chapter

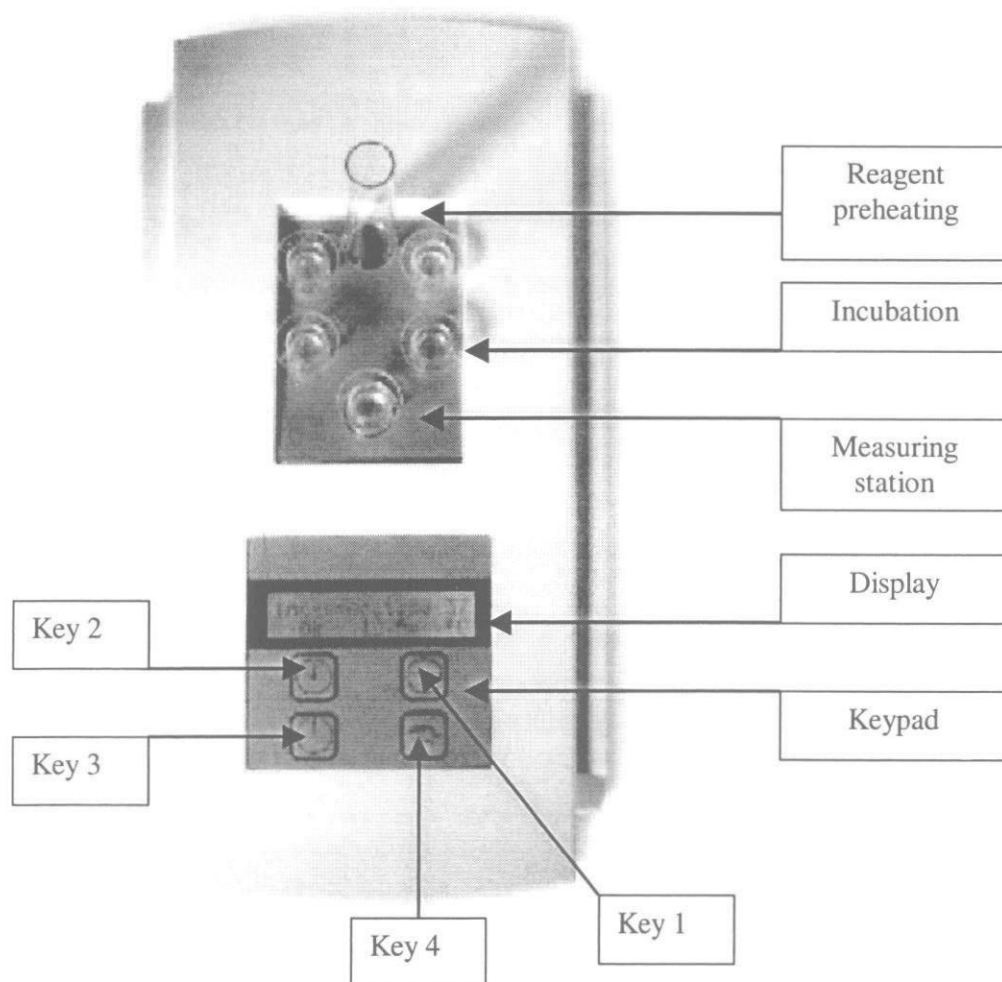


Item number

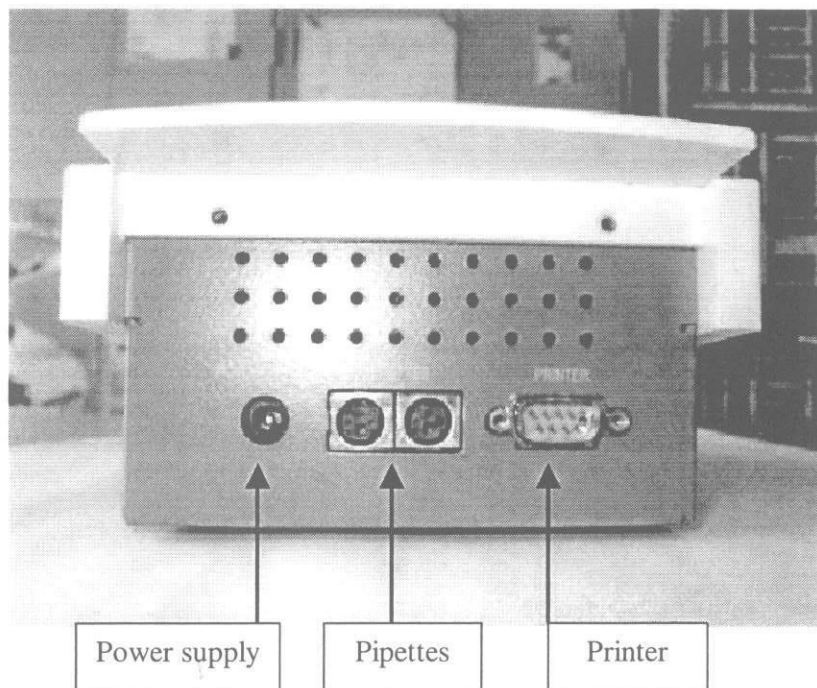
(H00000)

2.4 Illustrations

2.4.1 Top view

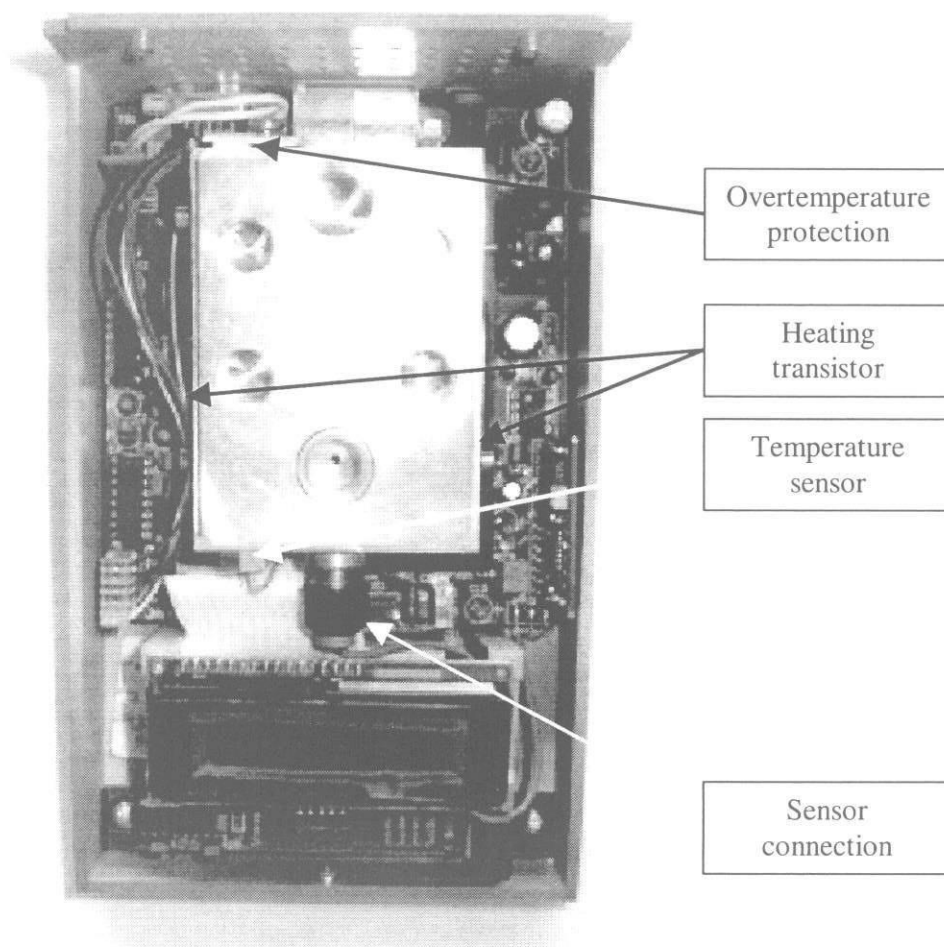


2.4.2 Rear view

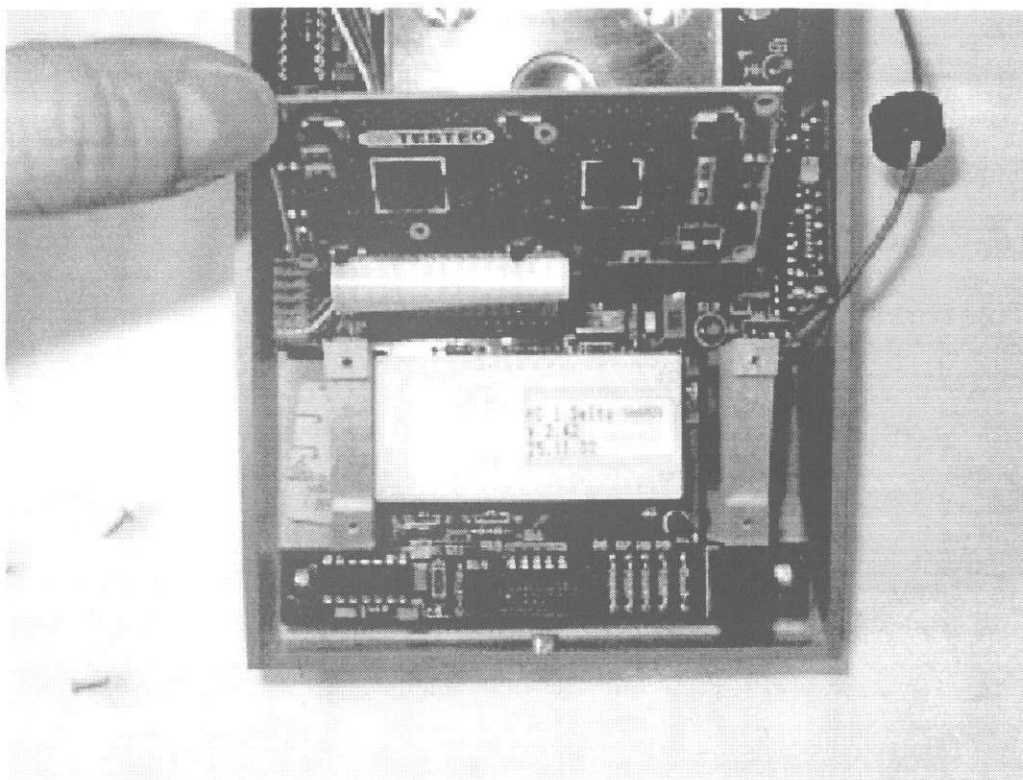


Rear view with connections

2.4.3 Internal view



2.4.4 Processor



Removing the fixing screws of the display allows access to the processor.

3. Safety recommendations

IMPORTANT!

Read these instructions carefully and follow them at all times!
Take note of warnings and recommendations!
This will avoid damage to equipment and personal injury!



3.1 General recommendations

If the KC1Δ displays faults which could endanger patient or operator it should not be used (IEC 61010).

Protective clothing, especially disposable gloves, must be worn. You may come into contact with infected plasma (hazardous substance).

Protective clothing, especially disposable gloves, that have been in contact with hazardous substances (e.g. infected plasma) must be disposed of immediately (Technical Rules for Hazardous Substances - *Technische Regeln für Gefahrstoffe* (TRGS)).

Plasma samples and reagents are special waste. The special waste must be disposed of in accordance with industrial instructions (laboratory regulations).

3.2 Recommendations for repairing the KC1Δ

The appliance must not be used for tests whilst under repair. If possible, the appliance must be disconnected from the power supply.

After the KC1Δ has been repaired control measurements are to be carried out to check the appliance is working properly. The measured values obtained must correspond to the reference ranges.

4. Accessories/equipment

The service software (S67300) is required to service the KC1Δ.

4.1 Tools

No special tools are needed to service the KC1Δ.

4.2 Measuring devices

The following measuring devices required to check the functions of the KC1Δ:

Standard measure	J10003
Magnetic field strength measuring device macro (FM1 macro) or Magnetic field strength measuring device macro (FM1 macro)	J03000 (230 Volt) or J03010 (110 Volt)
Thermometer	
Digital multimeter	
Storage oscilloscope	
Current measuring adapter	J01825

5. Measuring method

The KC1Δ is an electro-mechanical clot recognition system. The system uses a special cuvette that contains a special steel ball. The sample is placed in the cuvette. After the appropriate incubation period the cuvette is placed in the measuring station of the KC1Δ. The measuring station rotates slowly, making the cuvette turn along its longitudinal axis. Since the cuvette is positioned at an angle in the measuring station, the ball always remains at the lowest point in the cuvette thanks to gravity and the magnetic field. Directly opposite the position of the ball is a magnetic sensor. When the appropriate reagent is added, a timer is started. When clotting begins, fibrin threads form in the sample-reagent mixture. These fibrin threads pull the ball from its position as determined by gravity. This change in position triggers an impulse in the magnetic sensor which stops the timer electronically.

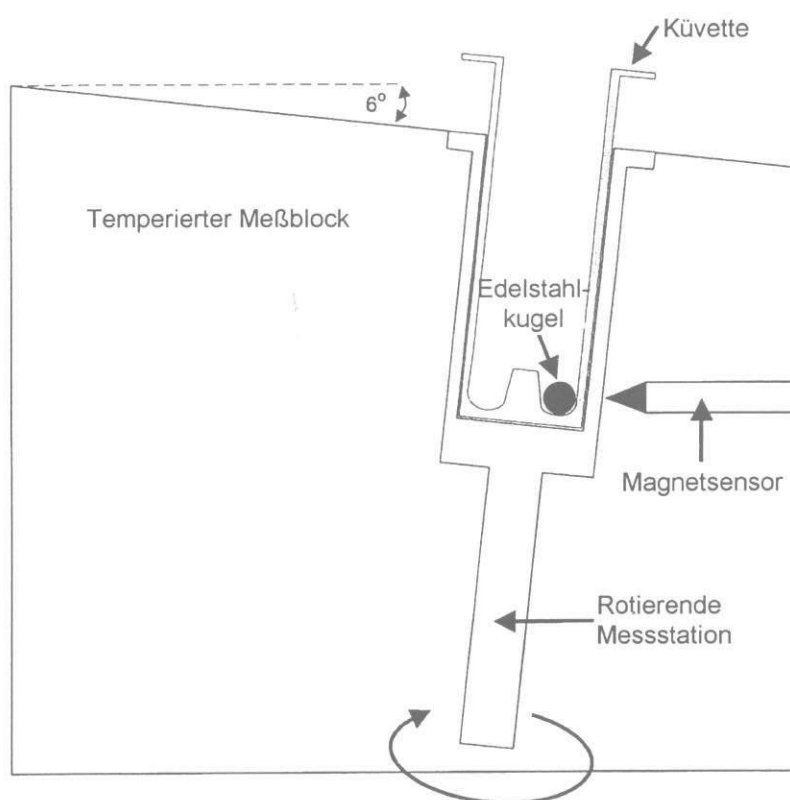


Diagram of the measuring system

6. Appliance installation

The KC1^Δ must be placed on a level, stable surface. The environment should be dust-free and at a fairly constant temperature. The appliance should not be used in strong draughts or in direct sunlight. The ventilation holes on the rear of the casing must not be covered.

WARNING!

Failure to observe these instructions could cause the KC1^Δ to malfunction!



Should the KC1^Δ malfunction, it must be ensured before carrying out any repairs that the environmental requirements described above have been satisfied. The appliance must be kept in a horizontal position at all times.

7. Disassembly

To disassemble the KC1Δ, remove the two screws on the rear and the screw on the front of the appliance.

The top cover can now be removed. When doing so make sure that the keypad is firmly attached to the top cover. Before completing removal, the connecting cable must be carefully unplugged from the "SW1" plug connector.

The keypad is glued onto the top cover. It can be removed to be replaced. Any remnants of glue which remain must be removed before gluing on a new keypad.

Remnants of glue must not be removed with cleaners that contain solvents!

The display must be taken off to remove the processor. The display is fastened to the appliance with 4 screws. Once these screws have been removed, the display can be carefully moved backwards. This will give you access to the processor. The display connecting cable should not be bent too much to prevent damage.

If the main board has to be removed from the appliance, the display should first be removed, followed by the 4 main board screws. The main board can now be removed from the lower part of the appliance together with the measuring module.

To remove the measuring module the 4 screws on the underside of the main board must be removed and all cable connections disconnected. The heating transistors are fastened to the measuring module with screws. These screws must also be removed to disassemble the unit. When refitting the measuring module make sure that the deflectors beneath the transistors are not damaged or off-centre. You should also make sure that there is an adequate layer of thermo-lubricant.

Hardware version 15.12.2000:

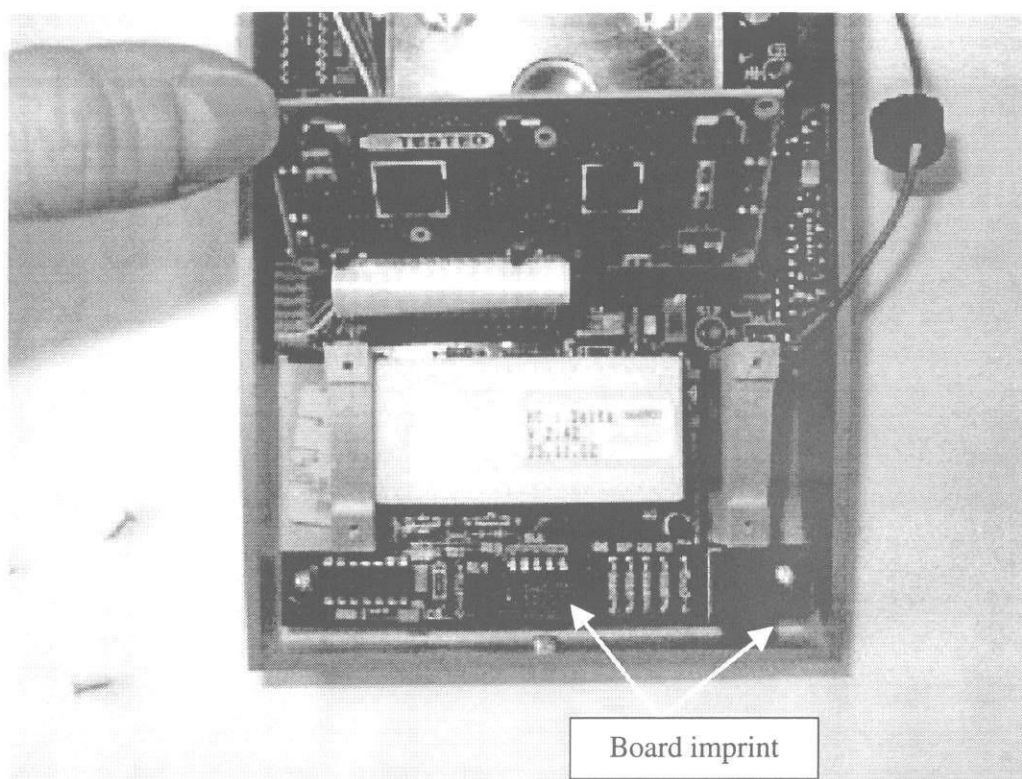
A total of 4 heating transistors are fitted. Three on the left of the measuring module and 1 on the right (viewed from above).

Hardware version 13.12.2001:

One transistor is fitted on the left.

8. Hardware differences and circuit description

8.1 Explanation of hardware differences



The hardware version used can be identified on the bottom edge of the main board of the KC1Δ. Two versions of the board were delivered:

- version **15.12.2000** and
- version **13.12.2001**

These versions differ in the following ways:

- number of heating transistors
- activation of heating transistors
- setting of heating current and measuring module temperature

In principle, this service manual is to be used for both versions. Explicit reference is made to where the versions are handled differently.

8.2 Circuit description

The KC1Δ consists of 6 large components:

- Power pack
- Keypad
- Display
- Main board
- Processor
- Measuring module

The appliance is powered by an external 12-Volt power pack. This power pack should always be completely replaced during servicing, as the power pack also provides protection as well as powering the appliance. Internally these 12 Volts generate a 5 Volt voltage. In addition, voltages of –12 Volt and –5 Volt are generated. These voltages should always be checked during servicing.



9.1

The processor is entirely responsible for controlling the appliance. All other components or parts are linked to the processor directly or via driver stages.

Keypad and display are directly linked to the processor.

The keypad is connected to pins 15-18. If one of the keys is pressed, a low level is applied.

The display is connected to pins 1-8, 32+33. The display contrast can be set using pot R3 (50 kΩ).

IC U1 is used to connect an external PC, e.g. for the service software. This is also where the –5 Volt voltage is generated.

The stepping motor is controlled by IC U10 and IC U8. A rectangular signal with c. 1 kHz generated by the processor is applied to pin 14 of IC10. This is converted and applied to the IC U8 output stages. The motor speed is given by the rectangular signal.

The temperature of the measuring module is scanned using the NTC R10 resistor.

Hardware version 15.12.2000:

The voltage released via the R10/R5 voltage divider is read in at pin 37 and converted to an 8-bit data value internally.

Here the temperature can only be set using the service software.



9.3+10.2

Hardware version 13.12.2001:

Here the voltage divider consists of R20, R5 and the R6 pot. The temperature is set to the required value with the R6 pot. Here too the voltage is read in at pin 37 and converted to an 8-bit data value internally.

The temperature should **only** be set with the R6 pot.



9.3

The heating of the measuring station module is controlled by a PWM signal from pin 11 in the processor. The lower the temperature of the measuring station module, the broader this signal. To avoid destroying the heating transistors, the maximum signal width is limited to a defined value.

Hardware version 15.12.2000:

The 4 parallel-switched heating transistors are controlled via pot R20 with the PWM signal. The maximum heating current is also set with pot R20.



9.2

Hardware version 13.12.2001:

Only one heating transistor is used in this version. Here the PWM signal is integrated with IC U11 and the transistor Q1 controlled with a direct voltage. It is no longer necessary to set the heating current.

In both versions there is overheating protection via TS1 and R22. The R22 polyswitch shuts down all heating if the current exceeds 3 A. The TS1 thermostatic switch shuts down the heating of the temperature of the measuring module reaches or exceeds 60 °C. The heating is switched back on once the module has cooled down.

The BZ1 acoustic sensor is controlled via pin 12 and transistor Q5. IC U9 provides the -12 Volt for the IC U5. Together with the U6 sensor, this hybrid module monitors the measuring pulses. If the movement of the special steel ball is detected by the beginning of clotting, the D9 LED lights up by way of a check.

The pipettes connected to connections J3 and J4 send the start signal to pin 13 of the processor.

9. Settings and tests

9.1 Testing operating voltages

at pin 11 KC-Sens	c. +12 V DC
at pin 8 KC-Sens	c. -12 V DC
at U2 pin 3	c. +5 V DC
at R2	c. -5 V DC

9.2. Setting heating current

From **software version 2.45** the current heat output [%] can be shown in the display. To do this, press and hold key 3 (bottom left) while switching on (key 1). This routine is ended with key 1. The KC1Δ then begins the measuring routine. This does not affect the following heating current setting.

9.2.1 Setting heating current from software version 2.31 of 05.07.2001 Hardware version 15.12.2000

Note: appliance temperature and room temperature c. 20 °C

Preparation:

An ammeter is to be connected to the supply lead of the KC1Δ.
(measuring adapter J01825)

Procedure:

Using pot R20 (2 KΩ) set the current consumption to 0.8 A after c. 1 minute.
(first heating stage)

After a further 3 minutes set the heating current to 2.2 A.
(second heating stage, heat output = 100%)

The current rises to c. 2.4 A until the end of the heating phase.
(end of heating phase after c. 9 minutes)

9.2.2 Setting heating current from software version 2.42 of 25.11.2002 Hardware version 15.12.2000

Note: appliance temperature and room temperature c. 20 °C

Preparation:

An ammeter is to be connected to the supply lead of the KC1Δ.
(measuring adapter J01825)

Procedure:

The current consumption is to be limited to 2.4 A with pot R20 (2 KΩ).

Monitor and if necessary adjust the current consumption until the end of the heat-up phase (c. 6 minutes).

From hardware version 13.12.2001 it is no longer necessary to set the heating current!

9.3 Testing and setting measuring module temperature

From **software version 2.45** the display temperature display can be altered in 1 °C steps to 0.2 °C steps to facilitate setting.

To do this, press and hold key 3 (bottom left) while switching on (key 1). This routine is ended with key 1. The KC1Δ then begins the measuring routine. This does not affect the following module temperature setting.

9.3.1 Testing and setting measuring module temperature Hardware version 15.12.2000

Note: measuring station module must be at operating temperature

Procedure:

A cuvette one-third filled with water is placed in an incubation position. The water temperature in the cuvette is measured with a thermometer. After c. 10 minutes the temperature should be 37.3 °C (± 0.5 °C).

The temperature can only be set using the service software.



10.3

Service software:

It is possible to correct the module temperature with the slide (see 10.1) in steps of c. 0.5 °C. Sliding to "+" increases the module temperature, to "-" lowers the temperature. A value corresponding to the correction is displayed in the little window underneath the slide.

If a temperature correction is made, this is to be checked again once the water in the cuvette has reached the new temperature. If necessary the equalisation carried out previously is to be repeated.

Temperature curve:

Please only change in single steps if the desired value cannot be achieved by correcting the module temperature!

The temperature curve is corrected via a pull-up/pull-down menu in the service software "Additional settings".



10.3

9.3.2 Testing and setting measuring module temperature Hardware version 13.12.2001

Note: measuring station module must be at operating temperature

Procedure:

A cuvette one-third filled with water is placed in an incubation position. The water temperature in the cuvette is measured with a thermometer. After c. 10 minutes the temperature should be 37.3 °C (± 0.5 °C).

The temperature is set with pot R6 (200 Ω) (not with the service software!). By way of compensation, the temperature shown in the display is to be set to the temperature measured.

When the water in the cuvette has reached the newly set temperature, this temperature is to be checked again. If the temperature value does not match, the previous compensation is to be repeated.

9.4 Testing measuring station speed

Measure the speed of the measuring station (40 rpm) with a stopwatch.

To do this, place a cuvette marked on the edge in the measuring station and count the revolutions with the appliance running.

The pulse-pause ratio of the motor control can be read off in the "Parameters" area using the service software.

If the appliance is functioning properly the values "61" for the speed and "59" for the pulse-pause ratio should be displayed.

The value displayed in the "Speed" field does not equate to the actual speed!

The actual speed can only be determined as described above. The speed is established by the oscillator frequency of the processor.

Should the displayed values not correspond to the reference values, default values can be written in the appliance in the "Settings" section in the service software and the "Send" button. If the speed does not correspond to the reference values after the default values have been sent, the appliance is faulty.



10.3

9.5 Mechanical setting of the sensor

In addition to a hall sensor, the sensor (X10009) also contains a permanent magnet, whose magnetic field acts on the steel ball in the cuvette with a defined force. The force is set by the distance of the sensor to the measuring station.

This setting is made by Trinity Biotech GmbH and must not normally be corrected.

The sensor setting can be checked with the field strength measuring device FM1 macro J03000 (230 V) or J03010 (110 V) from Trinity Biotech GmbH.

To check the magnetic field strength the measuring module of the KC1^Δ and the magnetic field detector of the FM1 macro must have an operating temperature of c. 37 °C.

The FM1 macro must be zero offset immediately prior to the test. This is done by pressing the zero key on the FM1 macro. It is important when doing this that the magnetic field detector is not near any magnetic field. It must not therefore be in the measuring station whilst performing the zero offset.

The magnetic field detector is now inserted into the measuring station and secured with the centring ring. The maximum value of the display can now be found by carefully turning the detector. This maximum value should be 92 ± 2 scale divisions.

If the value is not correct or if the sensor has to be replaced, the sensor lock nut has to be removed. The magnetic field can be set to 92 scale divisions by rotating the sensor forwards and backwards.

Then secure the sensor with the lock nut.

The sensor setting should be re-checked after every zero offset.

The electrical gain must be reset after any mechanical sensor adjustment.

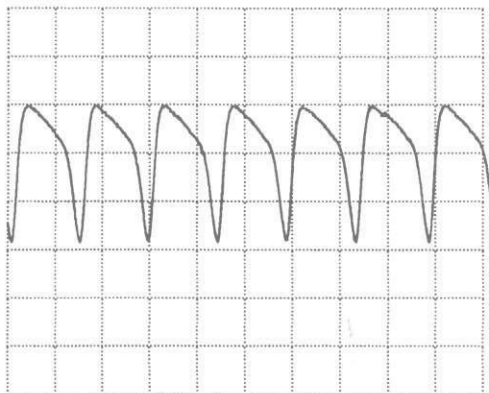
9.6 Setting the electrical gain

Note: measuring station module must be at operating temperature

First the standard measure from Trinity Biotech GmbH (J10003) is inserted into the measuring station to the bottom of the measuring beaker and secured with the centring ring.

The voltage measured by J5 at MP1 is set to 3 V_{ss} by means of a storage oscilloscope and a 1:1 probe with the pot situated on the KC-Sens hybrid.

It is important here that the measurement is made with the "DC" setting, so as not to falsify the result.



DATE: 28.02.2003
TIME: 09:57

SIGNALPARAMETER:

CH2 - VOLTS/DIV:=1V
CH1 - VOLTS/DIV:=1V
TIMEBASE-SEC/DIV:=1s
TRIGGERLEVEL CH1:AUTO
PRETRIGGER :0%
DELTA CURSOR :OFF
ADD CH1,CH2 :ON

PRINTERPARAMETER:

ZOOMRANGE - CH1:0-9
HARDCOPY SOURCE :HM 408

REMARKS:



Measuring signal with standard measure measured at MP1

9.7 Setting the LCD display contrast

The contrast of the LCD display can be adjusted using pot R3.

9.8 Setting the language

It is possible to set the language using the service software.



10.3

From **software version 2.45** it is also possible to switch between English and German directly on the KC1Δ.

To do this, press and hold key 2 while switching on (key 1).

You can choose between English and German using keys 2 and 3. The language setting is saved with "OK" (key 4). This routine is then complete and the measuring routing begins.

10. Service software (S67300)

10.1 General

The service program is required with the KC1^Δ to check and correct the appliance settings.

The program can run on PCs with the operating systems Windows 95 B, 98, 2000 and XP.

However, the PC must have a serial interface (COM1). If several serial interfaces are available, you can choose between COM1 - COM4 in the menu point "**Program / Interface**".

The service program in German and English is located together with the relevant Help file in a separate director on the enclosed CD.

The file **Service_e.exe** (English) or **Service_d.exe** (German) can be run from the CD.

Similarly, the directory with the desired language version can be copied on the hard disk of a PC and the program run from there.

The program is operated with the mouse.

KC 1 Delta Service Programm

Programm ?

Einstellungen | Parameter

Korrektur Blocktemperatur

Temp. Kurve: 220

Timeout (Sek.): 5

Sprache: englisch (1)

Standard Wert (PT): 0.0

ISI Wert (PT): 0.00

Übertragung:

Senden

Gerätedaten lesen

online COM-Port: 1 Version 2.50 Trinity Biotech GmbH j.m. 2003

10.2 Application

Switch on the KC1Δ and make the connection between the KC1Δ printer jack and the PC with the serial cable. No incubation time or measurement must be started. Start service program by double-clicking.

The program display windows now show default values.

These values can be sent to the appliance to completely reprogram a KC1Δ by clicking on “**Send**”.

The current appliance data is read in and displayed by pressing the button “**Read appliance data**”.

While the data is being read in the green light next to the read button becomes darker for c. 1 second, then becomes brighter again.

If the light remains dark, there is an error in the transfer (wrong interface selected, cable not OK, etc.). Rectify the problem and read the data in again.

The limits of the data can be altered with the assigned control elements.

All data is transferred to the KC1Δ by clicking on the “Send” button.

The transfer status is displayed by a progress indicator and lasts around 30 seconds.

10.3 Setting options

Correcting the module temperature (default value = 6):

Hardware version 15.12.2000: The module temperature is corrected via the slide.



10.01

9.3

Temp. curve (default value = 220):

Hardware version 15.12.2000: reducing the value increases the module temperature and vice versa.



9.3

Timeout (default value = 5 sec.):

Time between end of incubation time and start of measuring

Setting range: 5 – 60 seconds.

Language (default value = English):

Choice of German / English for KC1Δ display.

Standard and ISI value: (for INR calculations in PT measurements):

The values are reset to zero during programming!

The setting must be made by the operator on the appliance.

IMPORTANT!

With the KC 1^Δ **software version V2.31** the data to be transferred to the appliance is only activated after the KC 1^Δ has been switched on/off!

A message therefore appears in the software following data transfer.

In versions >V2.31 the data is automatically saved and activated after transfer.

It is not necessary to switch the appliance on/off.



10.4 “Parameter” register card

The appliance settings are displayed here as numbers by clicking on the “**Read appliance data**” button.

11. Spare parts

Part No	Description
G51000	PC Board KC1 Delta (Version 15.12.00)
G51001	PC Board KC1 Delta (Version 13.12.01)
X10082	Sensor plug AN 150mm cable
247571	Display 2x16 characters STN LED
218725	IC 7805 voltage regulator TO-220
221004	Socket 3pol Mini-DIN mounted
222009	Plug 9pinned SUB-D 90°
221005	Voltage supply socket Kycon
240042	Buzzer Piezo KC1 Delta
232935	Flex-Strip-Jumpers 16pol RM2.5
271168	Cable array bw 0.93x50 lug M3
144015	Casing (upper section) KC1 Delta
144016	Casing (lower section) KC1 Delta
X10022	Measuring cup KC1A complete
241111	Stepper motor 35 NI 48 S
X10009	Sensor KC (AN)
121505	Thermal cut-off bracket
121225	Seal Thermoblock KC1 Delta
120507	Drive belt KC1A no.282006
121562	Thermal cut-off switch P82 60 5
211010	Resistor NTC temperature control probe
111046	Pulley KC1A motor
113472	Cover EMV MiniDIN-socket
122059	Cover EMV 9pol Sub-D
615191	Block protection foil KC1A
245535	Power supply 12V 70W KC Delta
244830	Foil keypad KC1Δ

12. Printer configuration

If it becomes necessary to reconfigure the DPU 414 printer, the service menu can be accessed by pressing the "Online" key while switching on.

The printer now gives the current settings. The individual items in the list can be changed by pressing the "Online" key. Pressing "Online" switches each option to "On". Pressing "Paper Feed" switches to "Off".

After every 8 entries the settings can be saved by pressing "Paper feed", "Online" jumps to the next 8 entries.

Below are the basic printer settings:

SW1:

(OFF)	:	Input = Serial
(ON)	:	Printing Speed = High
(ON)	:	Auto Loading = ON
(OFF)	:	Auto LF = OFF
(ON)	:	Setting Command = Enable
(OFF)	:	Printing
(ON)	:	Density
(ON)	:	= 100%

SW2:

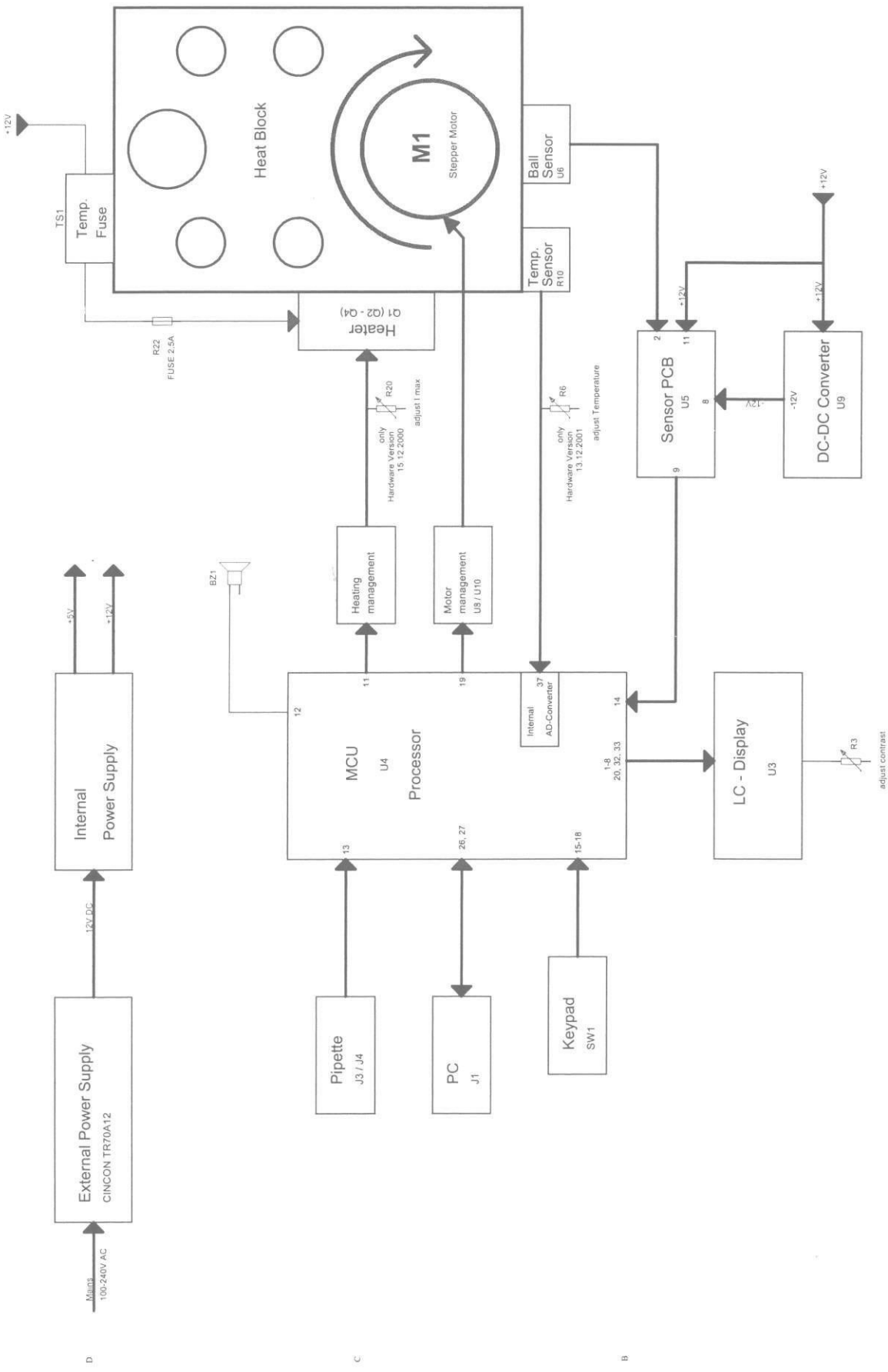
(ON)	:	Printing Columns = 40
(ON)	:	User Font Back – up = ON
(ON)	:	Character Select = Normal
(ON)	:	Zero = Normal
(ON)	:	International
(ON)	:	Character
(ON)	:	Set
(OFF)	:	= U.S.A.

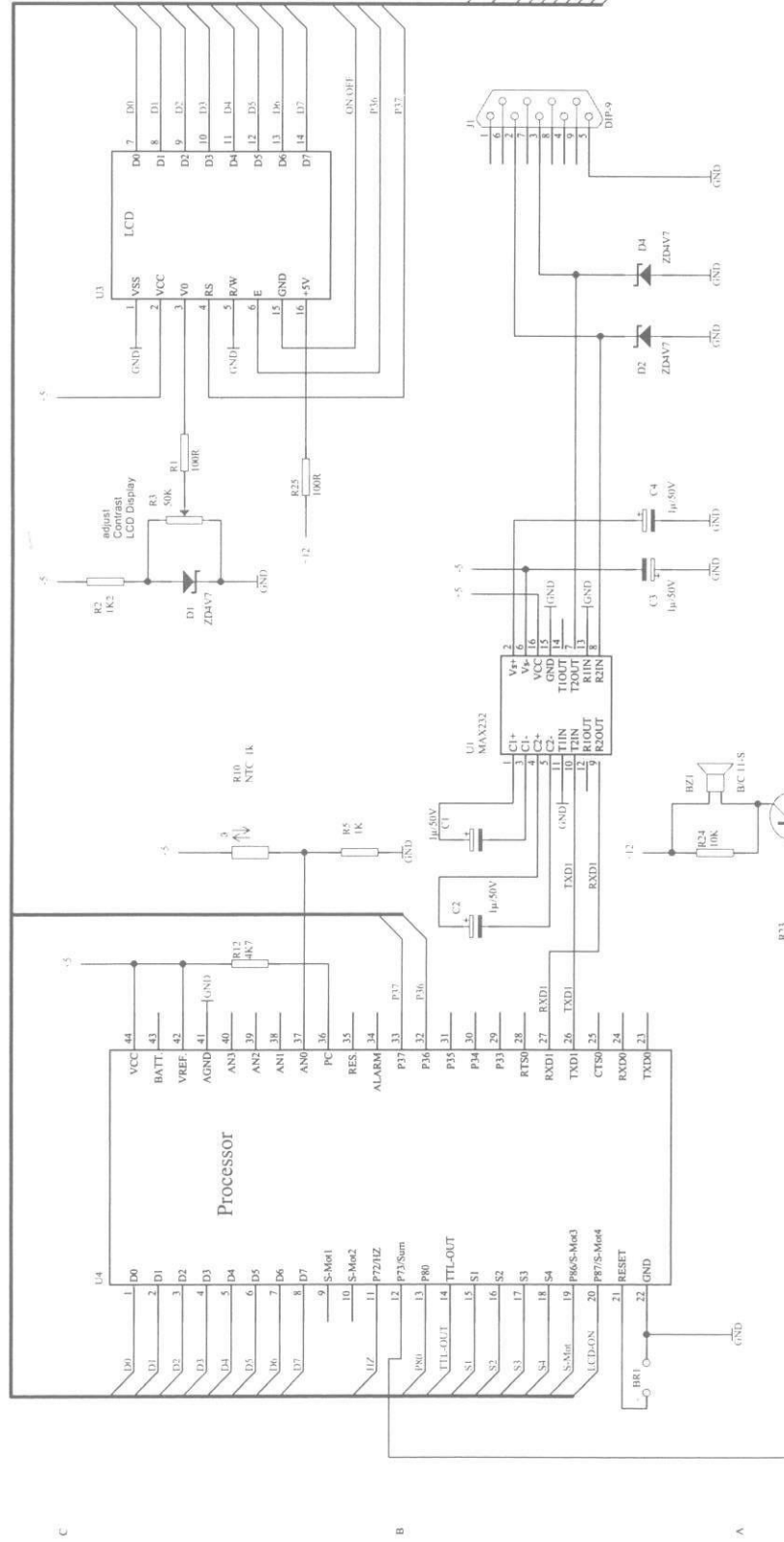
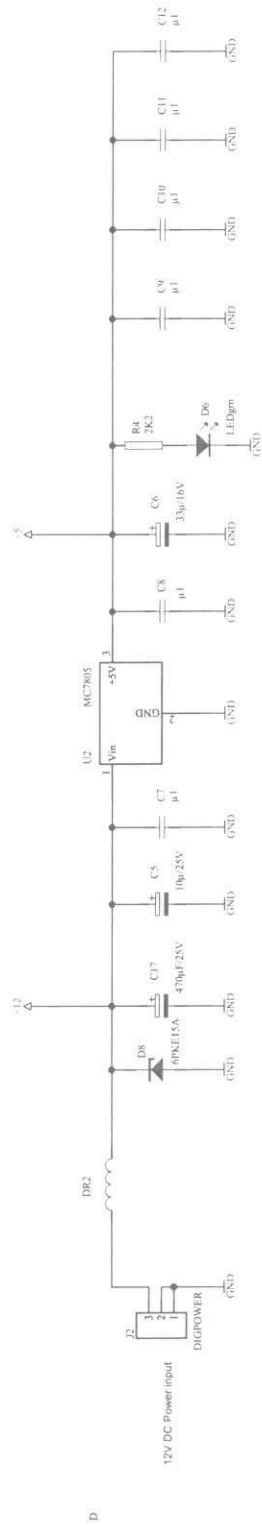
SW3:

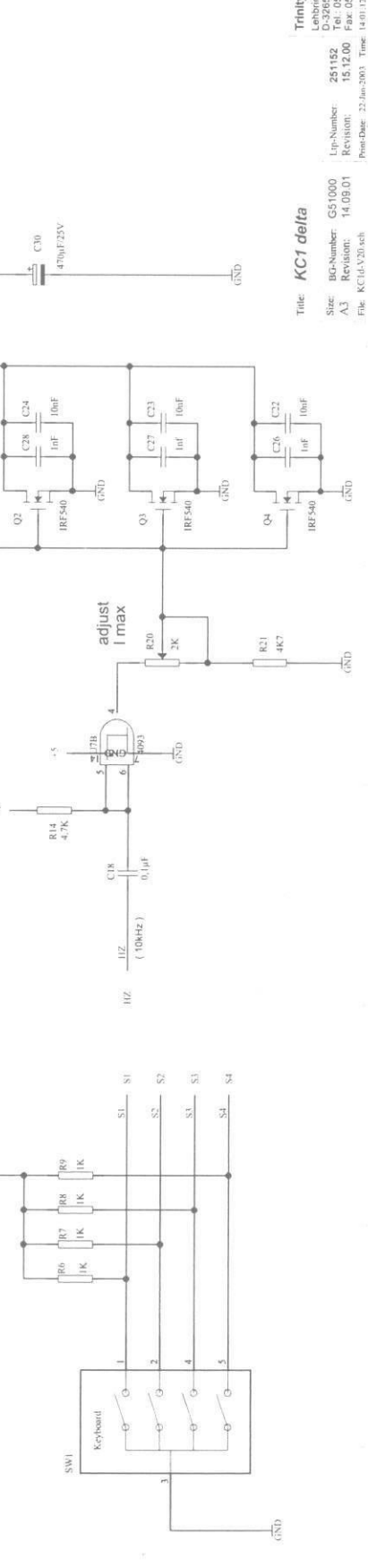
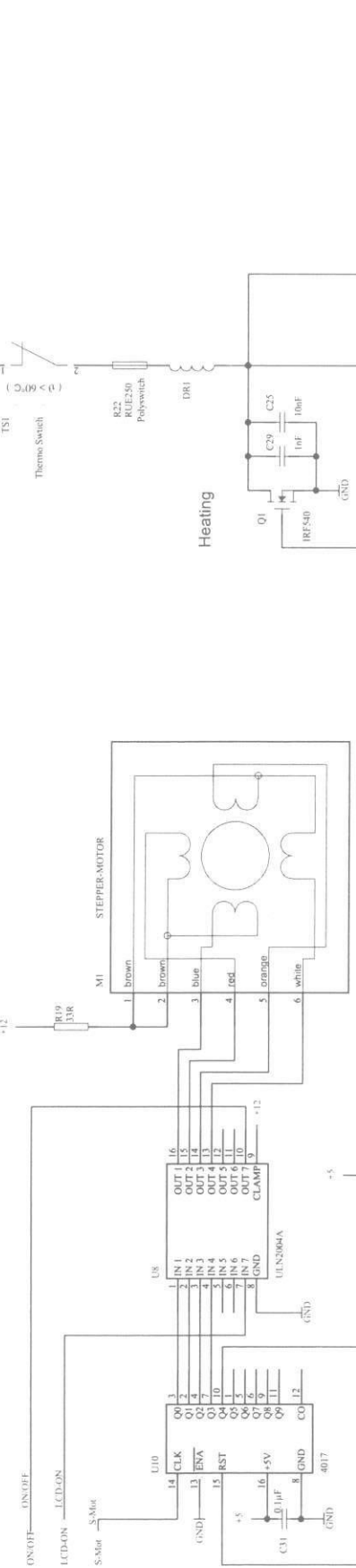
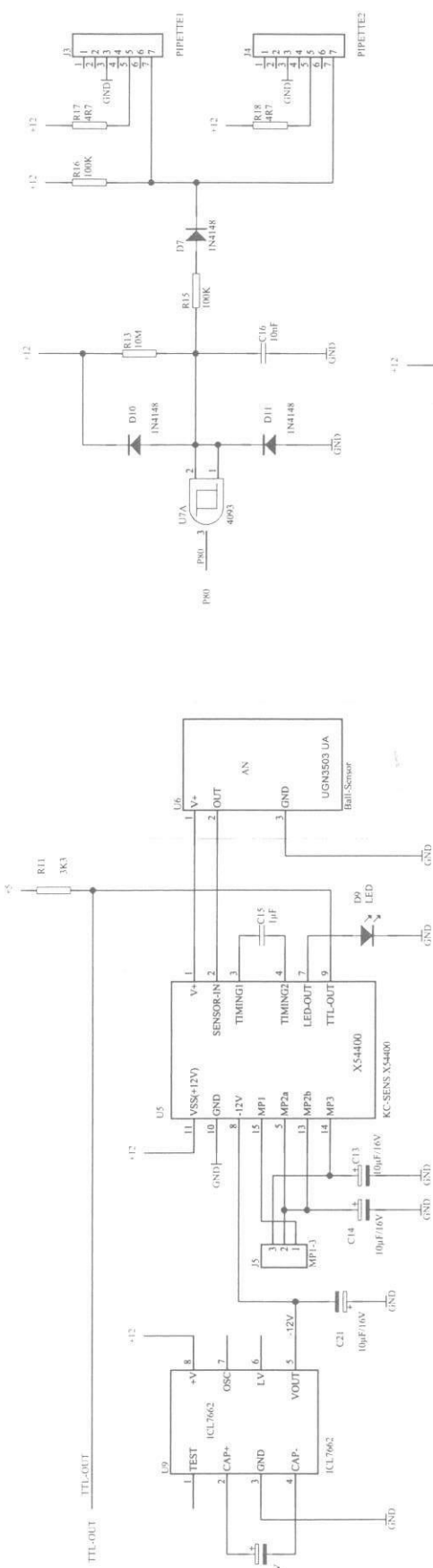
(ON)	:	Data Length = 8 Bit
(ON)	:	Parity Setting = NO
(ON)	:	Parity Condition = ODD
(ON)	:	Busy Control = H/W Busy
(OFF)	:	Baud
(ON)	:	Rate
(ON)	:	Select
(ON)	:	= 9600 Bps

13. KC1Δ plans and drawings

- Block diagram KC1delta..... 05.02.03
- Circuit diagram G51000 (2 pages) 09.07.03
Hardwareversion 15.02.00
- Mounting plan G51000 KC1delta Mechanical Layer 4..... 15.12.00
- Circuit diagram G51001 (page 1) 09.07.03
Hardwareversion 13.12.01
- Circuit diagram G51001 (page 2) 13.12.01
- Mounting plan G51001 KC1delta Bestückung Top 13.12.01
- Exploded drawing KC1delta







Title: KC1 delta
Size: BG-Number: G51000
A3 Revision: 14.09.01
File: KC1delta.v20.sch
Trinity Biotech
Lehrstuhl 59
D-39657 Lango
Tel: 05261/963-0
Fax: 05261/963-112
Lip-Number: 251152
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